PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Michael S. H. Chu et al.	Confirmation No.:	6707
Serial No.:	09/430,050	Examiner:	A. Lam
Filing Date:	October 29, 1998	Group Art Unit:	1641
Docket No.:	1001.1258101	Customer No.:	28075
For:	SPLIT VALVE FOR PEEL-AWAY SHEATH		

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APPEAL BRIEF UNDER 37 C.F.R. § 1.192

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By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 1.192, Appellant hereby submits this Appeal Brief in triplicate in furtherance of the Notice of Appeal filed on June 30, 2004. Enclosed herewith is a check in the amount of $330.00 to cover the fee prescribed by 37 C.F.R. § 1.17(c). Permission is hereby granted to charge or credit deposit account number 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, Minnesota 55311. An assignment from the inventors, Michael S. H. Chu and Yem Chin, conveying all right, title and interest in the invention to SciMed Life Systems, Inc., has been recorded at Reel 010359, Frame 0597.

II. RELATED APPEALS AND INTERFERENCES

Neither Appellant, Appellant's legal representatives, nor assignee know of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-9, 11-15 and 21 stand finally rejected under 35 U.S.C. §102(e) as anticipated by Heck (U.S. Patent No. 6,083,207).

The Appellant hereby appeals the final rejection of all pending claims 1-9, 11-15 and 21.

IV. STATUS OF AMENDMENTS

An After Final Amendment was filed February 27, 2004 concurrently with a Petition under 37 CFR § 1.181 to Withdraw Finality of Office Action. A Decision denying said Petition was mailed June 18, 2004. Examiner Lam indicated via telephone that an Advisory Action had been mailed June 17, 2004. The Advisory Action was never received by Appellants. Examiner Lam provided a courtesy copy of the Advisory Action on August 24, 2004, which does not

indicate it was actually mailed to Appellant. The Advisory Action appears to indicate that the After Final Amendment filed February 27, 2004, was not entered. Thus, as discussed at M.P.E.P. § 1207, Appellants file herewith an Amendment under 37 C.F.R. § 1.116 canceling claims 16-20 and 22-31.

V. SUMMARY OF INVENTION

The invention relates to valves, or more particularly breakaway valves, that can be used in conjunction with a peel-away valve sheath. The valve can include a breakaway valve body adapted to mate with an introducer sheath and structure for releasably compressing a compressible valve sleeve. Compressing the valve sleeve can restrict fluid flow through the valve sleeve. Please see, for example, page 3, lines 1-9 of the specification.

Turning now to the pending claims, claim 1 recites a valve (Figures 1, 2, 2A and 3, reference numbers 20, 120, and 220) for a tubular peel-away sheath (Figures 2 and 2A, reference number 54) that has a lumen (please see, for example, page 9, lines 10-13 of the specification) extending therethrough. The valve includes a valve body (Figures 1, 2, and 2A, reference numbers 22 and 122) that itself has a lumen (Figures 1 and 2, reference number 30) therethrough. The valve also includes means for preferentially breaking the valve body (Figures 1, 2 and 2A, reference number 26) along a predetermined location in response to applied force such that the valve body lumen splits open upon breaking the valve body. The valve further includes means for coupling the valve body to the peel-away sheath (please see page 7, line 21 through page 8, line 7 of the specification) for coupling the peel-away sheath lumen to the valve body lumen. The valve further includes a compressible valve sleeve (Figures 1, 2 and 2A, reference numbers 24 and 124) and means for receiving the compressible valve sleeve (Figure 1, reference number

32). The compressible valve sleeve has a proximal end (Figures 1 and 2, reference number 50), a distal end (Figures 1 and 2, reference number 48), and a lumen (Figures 1 and 2, reference number 52) that is adapted to receive a distal portion of a medical device. The valve includes means for compressing the valve sleeve (Figures 1 and 2, reference numbers 40 and 240) in order to restrict fluid flow from the peel-away sheath lumen through the valve and through the valve sleeve lumen. Claim 1 further recites that the proximal end of the compressible valve sleeve extends proximally of the means for compressing the valve sleeve.

Claim 2, which depends from claim 1, further recites that the valve sleeve includes a free end that extends past the means for compressing and also includes means for receiving a catheter tip within the valve sleeve lumen free end while the means for compressing is compressing the valve sleeve, such that the valve sleeve lumen is substantially occluded by the inserted catheter tip while the catheter tip is inserted (please see, for example, page 9, lines 17-18 and page 11, lines 3-7 of the specification, as well as Figures 2 and 2A).

Claim 3 is an independent claim reciting a breakaway valve (Figures 1, 2 and 2A, reference numbers 20, 120 and 220) for a tubular peel-away sheath (Figures 2 and 2A, reference number 54), where the sheath has an external surface, a lumen (please see page 9, lines 10-13 of the specification), and a proximal end (Figure 2, reference number 56). The breakaway valve includes means for reversibly restricting fluid flow from the sheath lumen, where the means for reversibly restricting fluid flow is coupled to the sheath proximal end. The means for reversibly restricting fluid flow includes a compressible valve sleeve (Figures 1, 2 and 2A, reference numbers 24 and 124) and means for compressing the valve sleeve (Figures 1, 2 and 3, reference numbers 40 and 240). The valve sleeve has a proximal end (Figures 1 and 2, reference number 50) and a distal end (Figures 1 and 2, reference number 48) and a lumen (Figures 1 and 2,

reference number 52) therethrough. The claim further recites that the proximal end of the valve sleeve extends proximal of the means for reversibly restricting fluid flow and that the proximal end of the valve sleeve is adapted to admit a catheter distal end into the valve sleeve lumen. The breakaway valve also includes means for breaking apart the fluid flow restricting means responsive to applied force.

Claim 4, which depends from claim 3, further recites that the means for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein the means for admitting the catheter distal end includes means for admitting the catheter distal end while the means for restricting flow is in the closed position (please see, for example, page 9, lines 17-18 and page 11, lines 3-7 of the specification, as well as Figures 2 and 2A).

Claim 5, which depends from claim 4, further recites that the means for restricting flow includes a flexible, constrictable tube having a lumen therethrough (please see, for example, Figures 1, 2 and 2A, reference numbers 24 and 124).

Claim 6, which depends from claim 5, further recites that the means for restricting flow includes means for pinching the flexible tube for constricting the flexible tube lumen (please see, for example, Figures 1 and 2, reference number 41).

Claim 7, which depends from claim 6, further recites that the means for pinching has at least two portions movable with respect to each other, the two portions having means (Figures 1, 2, 2A and 3, reference numbers 40 and 240) for accepting and pinching the flexible tube therebetween, the two portions together having an open position and a closed position (please se for example page 7, lines 8-12 of the specification).

Claim 8, which depends from claim 7, further recites that the movable pinching member

portions are hingedly coupled together with at least one hinge (Figures 1 and 4, reference numbers 42 and 342).

Claim 9, which depends from claim 8, further recites that the sheath has a longitudinal axis and the at least one hinge has an axis substantially parallel with the sheath longitudinal axis and the hinge enables movement of the pinching member portions about the hinge longitudinal axis for pinching the flexible tube in the closed position (please see, for example, page 11, line 21 through page 12, line 7 of the specification).

Claim 11, which depends from claim 8, further recites that when in the closed position, the pinching members include means (Figure 1, reference number 41) for leaving sufficient space in the flexible tube lumen for passage of a guide wire.

Claim 12 is an independent claim reciting an introducer sheath assembly for introducing a catheter distally into a human body. The introducer sheath assembly includes a tubular, distal introducer sheath (Figure 2, 2A, reference number 54) that has a proximal region (Figure 2, reference number 56) and a lumen extending therethrough (please see, for example, page 9, lines 10-13 of the specification). The introducer sheath includes at least one longitudinal strip for preferentially tearing the sheath along the strip. The introducer sheath assembly also includes a tubular, compressible, proximal valve sleeve (Figures 1, 3, 2A, reference numbers 24 and 124) having a proximal region (Figures 1 and 2, reference number 50), a distal region (Figures 1 and 2, reference number 48), and a lumen (Figures 1 and 2, reference number 52) therethrough. The introducer sheath assembly also includes a valve body (Figures 1, 2 and 2a, reference numbers 22 and 122) that has a lumen (Figures 1 and 2, reference number 30) therethrough and that is sealingly coupled to the introducer sheath proximal region. The claim recites that the valve includes at least one weakened region (Figure 1, reference number 34) for preferentially splitting

the valve into at least two pieces responsive to an applied breaking force.

The claim further recites that the valve body has a seat (Figure 1, reference number 32) for mating to the proximal valve sleeve distal region. The valve body includes a pinch member for pinching the flexible valve sleeve and has a closed position for constricting fluid flow through the valve sleeve and an open position for admitting a catheter inserted through the valve sleeve. The proximal region of the proximal valve sleeve extends proximal of the pinch member and is adapted to receive a medical device.

Claim 13, which depends from claim 12, further recites that the flexible valve sleeve includes a free portion proximal of the pinch member for admitting the catheter into the sleeve free portion while the pinch member is in the closed position (please see, for example, page 9, lines 17-18 and page 11, lines 3-7 of the specification, as well as Figures 2 and 2A).

Claim 14, which depends from claim 12, further recites that the valve body pinch member includes a recess therein for allowing passage of a guide wire through the pinch member while the pinch member is in the closed position (please see, for example, page 7, lines 15-20 of the specification as well as reference number 41 in Figures 1 and 2).

Claim 15 is an independent claim reciting a breakaway valve body (Figures 1, 2, 2A and 4, reference numbers 22, 122 and 322) for restricting flow from a peel-away introducer sheath (Figures 2 and 2A, reference number 54) that has a proximal region (Figure 2, reference number 56) and a lumen (please see, for example, page 9, lines 10-13 of the specification) therethrough. The breakaway valve body includes a breakaway distal portion (Figure 1, reference number 28) that has a lumen extending therethrough for receiving the introducer sheath proximal region. The breakaway valve body also includes a proximal portion having two opposed valve body members (Figure 4, reference numbers 336 and 338).

At least one of the valve body members are movable relative to the other and the valve body members have concave surfaces therebetween that are adapted to receive a flexible valve sleeve (Figures1, 2 and 2A, reference number 24 and 124) therebetween. The claim further recites that the opposed valve body members have an open position and a closed position (please see, for example, Figure 4). The opposed valve body members move apart relative to each other to reach the open position and move together relative to each other to reach the closed position. The flexible valve sleeve has a lumen therethrough that is adapted to receive a medical device. The flexible valve sleeve has a proximal end extending proximally of the body members, and a distal end. The claim further recites that the sleeve is compressible and that the sleeve and the sleeve lumen are constricted between the body members in the closed position such that fluid flow through the sleeve is substantially restricted in the closed position (please see, for example, page 12, lines 2-6 of the specification).

Claim 21, which depends from claim 15, further recites that the valve body members are pivotally mounted to each other along at least one hinge (Figure 4, reference number 342) oriented substantially parallel to the valve body lumen longitudinal axis (please see, for example, page 11, lines 21-23 of the specification).

VI. ISSUES

1. Whether claims 1-9, 11-15 and 21 are patentable over Heck (U.S. Patent No. 6,083,207).

VII. GROUPING OF CLAIMS

Pursuant to 37 C.F.R. § 1.192(c)(7), Appellant asserts that claims 1-9, 11-15 and 21 stand together.

VIII. ARGUMENT

In order to anticipate, the cited reference must disclose each and every claimed element. Heck fails to do so. Claim 1 is directed to a valve for a tubular peel-away sheath. Claim 1 recites, among additional elements, the following structural elements:

> a compressible valve sleeve having a proximal end, a distal end, and a lumen adapted to receive a distal portion of a medical device; and
>
> means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through said valve and valve sleeve lumen, said proximal end of said compressible valve sleeve extending proximal of said means for compressing said valve sleeve.

It can be seen that claim 1 requires the presence of a compressible valve sleeve. Heck does not describe a compressible valve sleeve. The Examiner has repeatedly referred to element (300) of Heck as being the equivalent of the claimed compressible valve sleeve. This is not correct. Heck describes element (300) as a dilator, and notes that element (300) can also be a catheter, a pacemaker lead or other medical device. However, as Appellants have discussed repeatedly in response to previous Office Actions, the compressible valve sleeve is distinct from the dilator, catheter or other medical device that is referred to in Heck.

The Examiner has stated that it must be true that the hemostasis valve of Heck compresses the dilator (300). *See* page 7 of the June 30, 2003 Office Action. It appears as though the Examiner is making an inherency argument, since an inherent characteristic is a characteristic that must be true. *See* M.P.E.P. §2112. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing

described in the reference, and it would be so recognized by persons of ordinary skill." M.P.E.P. §2112, citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Thus, in the case of the Heck patent, it must necessarily be true that the device (300) is compressed in the valve body. However, as will be discussed in greater detail hereinafter, a hemostasis valve in general, and specifically the hemostasis valve in Heck, is a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device. Thus, it is not inherent that a hemostasis valve, including the hemostasis valve in Heck, compresses a device that is being passed through the valve body.

Because a hemostasis valve does not inherently or otherwise compress a device that is passed through the body of the valve, and Heck uses this standard definition, Heck does not disclose a valve that compresses "said valve sleeve for restricting fluid flow." It is respectfully asserted that, according to the legal doctrine from *In re Robertson* and M.P.E.P. §2112, compression of a compressible valve sleeve is not inherent in Heck.

Moreover, the claim language "must be given [its] plain meaning unless applicant has provided a clear definition in the specification." M.P.E.P. §2111.01. "Words in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning." M.P.E.P. §2111.01, citing *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983).

To state that a "compressible valve sleeve" in the claims of the current invention is the equivalent of a medical device that is referred to in Heck would give the phrase "compressible valve sleeve" a meaning other than the meaning attributed to the phrase by one skilled in the art. Specifically, one skilled in the art would not compress a medical device such as a dilator or a catheter. These medical devices do not operate well if kinks or bends are put in them, as it can

affect their pushability through the vasculature and steerability through tortuous pathways. These devices are made to exacting standards that enable them to be effectively advanced through a body lumen, and one skilled in the art would not knowingly make these devices less effective by compressing them.

One skilled in the art would not use a catheter for the compressible valve sleeve because the compression of the catheter would not allow for the operator to "feel" the progress of the catheter through the body lumen. In addition, the expense of a device such as a catheter or a dilator would prevent one of ordinary skill in the art from compressing such a device in the current invention when a compressible valve sleeve that is not a medical device would suffice. Finally, when a medical device with a lumen is used, it is desirable to keep the lumen open in order to maintain the functionality of the device.

Thus, for all of the above reasons, one skilled in the art would not use a medical device such as a catheter or dilator in place of the compressible valve sleeve. According to M.P.E.P. §2111.01 and *In re Sneed*, this definition must be used unless the patent clearly states an alternate definition. Because the current invention does not state an alternate definition, the definition that should be given a "compressible valve sleeve" should not be a medical device such as a dilator or a catheter. Thus, for at least this reason, claim 1 is patentable over Heck.

It can be seen that claim 1 also requires the presence of means for compressing the valve sleeve for restricting fluid flow from the peel-away sheath lumen through the valve and valve sleeve lumen. There is no structure in the Heck device that performs this function. The Examiner has repeatedly asserted that the neck opening (52) and lips (56) of the Heck device "compress" a device such as a catheter that is placed in the valve. This interpretation is contrary to the specific teachings in Heck.

In column 5, lines 53-57, Heck states that the sections of the valve are "formed from a conventional hemostasis valve material, such as a pliant, resilient rubber, such as silicon rubber, latex rubber or a foamed rubber." Heck goes on to describe the outside wall of the valve sections as providing "space for lips (56) to separate without excessive force being applied, as the medical device passes through the lips (56)." See column 6, lines 44-46. Heck also describes the outside wall sections as serving to "prevent the lips from opening when no pressure is place on them by the medical device." See column 6, lines 60-62. These passages clearly describe a hemostasis valve with pliant valve sections that are deformed or compressed by the device such that they form a seal around the device. Thus, the device disclosed by Heck is structurally and functionally different from the claimed device.

The claimed valve of claim 1 includes a compressible valve sleeve with a lumen, and a means for compressing that valve sleeve lumen to the extent that fluid flow through the lumen is restricted. The device of Heck fails to teach a structure that performs this function. The Examiner asserts that the lips (56) of the Heck valve "compress" a medical device such as a catheter that is placed between them. Appellants submit that there is no teaching or suggestion in Heck that the valve lips are structured such that they would or could compress a catheter to the extent that fluid flow through it was restricted. The entire disclosure of Heck is directed to the device acting like a conventional hemostasis valve, which forms a seal around the device within the valve. Additionally, because Heck teaches the valve as suitable for holding a pacemaker lead, one of skill in the art would understand that the Heck valve does not compress the device within the valve, but rather the valve itself is compressed or deformed to form a seal around the device.

The Examiner has asserted that "compressible" is defined as capable of being compressed, and the catheter or other medical device described by Heck is considered "capable of being compressed". The Examiner also has stated that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to be patentably distinguished.

Appellants submit that the claimed device does contain structural differences that distinguish it over the device of Heck. The independent claims recite the limitation that the valve has a means for compressing the valve sleeve for restricting fluid flow through the valve sleeve lumen. The claimed device thus has a structural feature that compresses the valve sleeve sufficiently to restrict fluid flow through it. While a catheter or other medical device may be capable of being compressed to some degree, there is absolutely no teaching or suggestion in Heck that the disclosed valve has a structure that would or could actually compress a catheter to the degree that fluid flow through it was restricted. Thus, Heck fails to disclose a claimed element and for at least this reason claim 1 is patentable over Heck.

The Examiner has repeatedly and in error asserted that Heck teaches a hemostasis valve that compresses the dilator (300). Such an assertion is contrary to the manner in which a hemostasis valve normally operates. Patent language must be read as those of ordinary skill in the art would interpret them. *See* M.P.E.P. §2111.01. As a general rule, "words in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning." *Toro Co. v White Consolidated Ind., Inc.*, 199 F.3d 1295, 1299 (Fed Cir. 1999). It must be determined "how a person of experience in the field of the invention would, upon reading the patent documents, understand the words used to define the invention." *Id.* Applicants respectfully assert that these

legal concepts from M.P.E.P. §2111.01 and the cases cited therein were not followed, and the Examiner is misinterpreting Heck.

Throughout the extensive prosecution of the present application, Appellants have attempted to demonstrate to the Examiner that Heck describes a valve that operates as a conventional hemostasis valve. A fundamental difference between the claimed valve and a conventional hemostasis valve is that the claimed valve is directed to compressing a compressible valve sleeve sufficiently to prevent flow through the valve sleeve. A conventional hemostasis valve, however, is constructed to prevent flow around the exterior of a device inserted through the hemostasis valve.

A standard hemostasis valve does not create a seal by compressing a device that is being passed through it. According to M.P.E.P. §2111.01 and *Toro*, as stated above, Heck must be read to use this standard definition unless Heck clearly indicates an alternate definition. Heck does not offer such an alternate definition and must be read to be using the standard definition of a hemostasis valve.

The standard definition of a hemostasis valve is a valve that can accommodate a device being passed through the body of the valve. Fluid flow around the device is prevented while the device is in the valve body. In addition, fluid flow through the valve is prevented after the device is removed because the valve returns to a closed position when the device is removed from the valve body. The medical device is not pinched off in the valve body to create the seal. Instead, a flexible membrane that seals around the medical device creates the seal. Because a standard hemostasis valve seals around a device that is passed through the valve, any lumen in a device that is being passed through the valve can be kept open while the device is in the valve body.

Indeed, Appellants have previously provided the Examiner with a detailed description, including medical textbook entries, of how conventional hemostatis valves work. The Examiner, however, has decided, apparently without merit or support, that the hemostasis valve taught by Heck "operates differently".

That Heck describes a valve that operates as a conventional hemostasis valve is abundantly clear to one of ordinary skill in the art. See, for example, column 9, lines 31-32 of Heck where the disclosed device is specifically described as "the partitioned hemostasis valve (14) acts like a conventional hemostasis valve." In view of this direct statement in Heck, one of ordinary skill in the art would interpret Heck as operating as a conventional hemostasis valve in preventing blood flow **around** the device inserted through the valve. As a further indication of the fact that the device of Heck functions by sealing around whatever is inserted through the valve, please see, for example, column 5, lines 33-35, where Heck describes the valve as configured to receive a dilator, catheter, pacemaker lead or other medical device. If the Heck valve can be used either with a catheter, which has a lumen, or a pacemaker lead, which one of ordinary skill in the art knows does not have a lumen, then Heck cannot possibly be construed to have means for compressing a valve sleeve for restricting fluid flow through the valve sleeve lumen, as is recited in the claims.

Appellants point as well to the following language in Heck at column 2, lines 14-32:

> One method of preventing, or at least limiting, the flow of blood out of a sheath while a pacemaker lead is being introduced is for the physician to place his thumb over the exposed end of the sheath or to squeeze or pinch the exposed end of the sheath between his thumb and forefinger. However, neither of these methods for reducing the undesired flow of blood and air through the sheath is desirable, because the opportunity for loss of blood and introduction of air is still present. In addition, the structure of these sheaths still requires the surgeon to hold onto it while it is in place in the vessel, thereby limiting the surgeon's ability to

> perform other medical procedures at the same time. Moreover, squeezing the exposed end of the sheath can deform or even break the sheath, making lead insertion difficult and increasing the likelihood of damage to the lead as it passes through the sheath. Further, even when holding the end of the sheath or pinching the sheath, flow of blood out of the sheath is not entirely stopped. (Emphasis added.)

The underlined portions of this quotation indicate that a device being passed through the valve should not be compressed or squeezed. This reinforces the accepted definition of a hemostasis valve; a hemostasis valve forms a seal around the device and does not form a seal by compressing the device. See also the following quotation from Heck at column 6, lines 43-53:

> In addition, by sloping inward toward the lip (56), the inwardly sloped portion (60) of the outside wall (58) provides space for the lips (56) to separate without excessive force being applied, as the medical device passes through the lips (56). The inwardly sloped portion (60) of the outside wall (58) preferably slopes at an angle of about 35 to about 75 degrees from the position of the upper portion (62) so that it places pressure on the lip (56) to hold it closed against the corresponding lip of the cooperating hemostasis valve section (40), even when the medical device is forced between the lips (56). (Emphasis added.)

Again, instead of an indication that the medical device is to be compressed, Heck has stated that the hemostasis valve is provided with a structure specifically designed to protect the medical device against compression. The first underlined portion indicates that the hemostasis valve described by Heck is provided with a structure to reduce the compression on a medical device. The second underlined portion indicates that a medical device is advanced through the valve lips (56), and does not provide any indication of compression of the medical device.

Appellants point as well to the following citation from Heck at column 5, lines 53-59:

> Each section (38, 40) of the partitioned hemostasis valve (14) is formed from a conventional hemostasis valve material, such as a pliant, resilient rubber, such as silicon rubber, latex rubber or a foamed rubber of 20 to 60 durometer, which can be shaped to fit

within the respective body sections (26, 28) of the partitioned hemostasis valve housing (12).

A hemostasis valve "is formed from a conventional hemostasis valve material," which is soft and can conform around any device that is passed through the valve. This is further reinforcement that the accepted definition of a hemostasis valve is a valve that does not compress a device that is being passed through the valve.

All of these passages from Heck further reinforce that a hemostasis valve is a valve that can accommodate a device being passed through it while sealing around, and not compressing, the device. Appellants do not understand the Examiner's continued insistence, contrary to all evidence, that Heck teaches a hemostasis valve that compresses element (300). Indeed, the Examiner has asserted that "the valve that Heck discloses must pinch the medical device in order to prevent blood flow." Clearly, the Examiner has misinterpreted the cited reference and thus has not correctly applied it to the claimed invention.

Claim 1 (and claim 2 depending therefrom) is clearly patentable over Heck, as Heck fails to disclose each and every claimed element.

Independent claim 3 is directed to a breakaway valve and recites a compressible valve sleeve and means for compressing the valve sleeve. As discussed with respect to claim 1, Heck completely fails to describe, at a minimum, these elements, Thus, claim 3 (and claims 5-11 depending therefrom) is clearly patentable over Heck.

Independent claim 12 is directed to an introducer sheath and recites a compressible valve sleeve and a pinch member for pinching the compressible valve sleeve such that fluid flow through the compressible valve sleeve is constricted. As discussed with respect to claim 1, Heck describes neither a compressible valve sleeve nor any structure for compressing or pinching the

compressible valve sleeve. Thus, claim 12 (and claims 13-15 and 21 depending therefrom) is clearly patentable over Heck.

Finally, Appellants assert that the anticipation rejection under 35 U.S.C. §102(e) of claim 12 is improper for an additional reason. Specifically, an anticipation rejection must be based on prior art that discloses each and every claimed element. "A claim is anticipated only if each and element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131, citing *Veredegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Appellants note that claim 12 recites a valve sleeve seat that receives an end of the compressible valve sleeve. The valve sleeve distal end abuts this valve sleeve seat (32), and thus the valve sleeve seat does not allow the compressible valve sleeve to be inserted into the tube (202) beyond the valve sleeve seat. *See* Specification at page 7, lines 8-9 and Figure 1.

Heck fails to disclose a valve sleeve seat. In fact, the dashed line in Figure 2 of Heck indicates that the device (300) can be inserted through the valve and into the tube (202). If there were a valve sleeve seat where the device (300) is designed to match up with the valve sleeve seat, the device (300) would not be able to extend through the valve body and into tube (202). In addition, Figure 1 of Heck shows the device (300) inserted in the hemostasis valve nearly up to the hub at the proximal end of the device (300). This means that the device (300) is extending through the valve and into the tube (202). Again, this would not be possible if the valve body contained a valve sleeve seat. Thus, Applicants respectfully assert that Heck does not disclose an element of claim 12. According to M.P.E.P. §2131 and *Verdegaal*, this lack of disclosure of an element shows that Heck does not anticipate this claim, and it should be allowable.

IX. CONCLUSION

For at least the reasons stated above, the rejection of claims 1-9, 11-15 and 21 under 35 U.S.C. §102(e) should be reversed.

Respectfully submitted,

Michael S. H. Chu et al.

By his attorney,

Date: 8/27/04

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X. APPENDIX OF CLAIMS

1. A valve for a tubular peel-away sheath having a lumen therethrough comprising:

a valve body having a lumen therethrough;

means for preferentially breaking said valve body along a predetermined location in response to applied force, such that said valve body lumen splits open upon breaking;

means for coupling said valve body to said peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen;

means for receiving a compressible valve sleeve;

a compressible valve sleeve having a proximal end, a distal end, and a lumen adapted to receive a distal portion of a medical device; and

means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through said valve and valve sleeve lumen, said proximal end of said compressible valve sleeve extending proximal of said means for compressing said valve sleeve.

2. A valve as recited in claim 1, wherein said valve sleeve includes a free end extending past said means for compressing, and further comprising means for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

3. A breakaway valve for a tubular peel-away sheath, said sheath having an external surface, a lumen, and a proximal end comprising:

means for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end, wherein said means for reversibly restricting fluid flow includes a compressible valve sleeve and means for compressing said valve sleeve, said valve sleeve having a proximal end and a distal end and a lumen therethrough, the proximal end of said valve sleeve extending proximal of said means for reversibly restricting fluid flow and adapted to admit a catheter distal end into said valve sleeve lumen; and

means for breaking apart said fluid flow restricting means responsive to applied force.

4. A breakaway valve as recited in claim 3, wherein said means for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position.

5. A breakaway valve as recited in claim 4, wherein said means for restricting flow includes a flexible, constrictable tube having a lumen therethrough.

6. A breakaway valve as recited in claim 5, wherein said means for restricting flow includes means for pinching said flexible tube for constricting said flexible tube lumen.

7. A breakaway valve as recited in claim 6, wherein said means for pinching has at least two portions movable with respect to each other, said two portions having means for accepting and pinching said flexible tube therebetween, said two portions together having an

open position and a closed position.

8. A breakaway valve as recited in claim 7, wherein said movable pinching member portions are hingedly coupled together with at least one hinge.

9. A breakaway valve as recited in claim 8, wherein said sheath has a longitudinal axis and said at least one hinge has an axis substantially parallel with said sheath longitudinal axis and said hinge enables movement of said pinching member portions about said hinge longitudinal axis for pinching said flexible tube in said closed position.

10. (cancelled)

11. A breakaway valve as recited in claim 8, wherein, when in said closed position, said pinching members include means for leaving sufficient space in said flexible tube lumen for passage of a guide wire.

12. An introducer sheath assembly for introducing a catheter distally into a human body comprising:

a tubular, distal introducer sheath having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip for preferentially tearing said sheath along said strip;

a tubular, compressible, proximal valve sleeve having a proximal region, a distal region, and a lumen therethrough; and

a valve body having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat for mating to said proximal valve sleeve distal region, said valve body including a pinch member for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve; wherein said proximal region of said proximal valve sleeve extends proximal of said pinch member and is adapted to receive a medical device.

13. An introducer sheath assembly as recited in claim 12, wherein said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position.

14. An introducer sheath assembly as recited in claim 12, wherein said valve body pinch member includes a recess therein for allowing passage of a guide wire through said pinch member while said pinch member is in said closed position.

15. A breakaway valve body for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough comprising:

a breakaway distal portion having a lumen therethrough for receiving said introducer sheath proximal region; and

a proximal portion including two opposed valve body members, at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible

valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, wherein said flexible sleeve has a lumen therethrough adapted to receive a medical device, said flexible sleeve having a proximal end, and a distal end, said proximal end extending proximal of said body members, said sleeve being compressible, and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

16-20. (cancelled)

21. A breakaway valve body as recited in claim 15, wherein said valve body members are pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis.

22-31. (canceled)

XI. APPENDIX OF AUTHORITIES CITED

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

In re Sneed, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983)

Toro Co. v White Consolidated Ind., Inc., 199 F.3d 1295, 1299 (Fed Cir. 1999)

Veredegaal Bros. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987)